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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,

Plaintiffs and Counterclaim-Defendants,

v.

ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,

Defendants and Counterclaim-Plaintiffs.

Civil Action No. 3:10-CV-01723-JAP-TJB

PLAINTIFFS' OPPOSITION TO
DEFENDANTS' MOTION IN LIMINE TO
PRECLUDE THE INTRODUCTION OF
EVIDENCE OF THE AVERAGE
PARTICLE DIAMETER OF FINE
GRANULES IN DEFENDANTS'
EXHIBIT BATCH TABLETS

CONTAINS HIGHLY CONFIDENTIAL MATERIAL – FILE UNDER SEAL

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## **TABLE OF AUTHORITIES**

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Pursuant to the Court's motion *in limine* briefing schedule, Plaintiffs submit its opposition to Defendants' Motion *In Limine* To Preclude The Introduction Of Evidence Of The Average Particle Diameter Of Fine Granules In Defendants' Exhibit Batch Tablets

(D.I. 295) ("Motion").

#### PRELIMINARY STATEMENT

Zydus seeks to exclude Plaintiffs' infringement evidence relating to average particle diameter measurements of Zydus' ANDA product ("Plaintiffs' APD Evidence"). In support of its Motion, Zydus makes two main arguments – one based on new claim constructions and a second that requires this Court to weigh Plaintiffs' infringement evidence before trial. Neither argument is appropriate at this phase.

First, Zydus yet again attempts to reopen claim construction of the particle size limitations in the asserted claims of the Takeda patents<sup>1</sup>. The Court previously construed each of the particle size limitations for the "fine granules" of the Takeda patents to include a  $\pm 10\%$  deviation. (See D.I. 113 at 7, 9,10<sup>2</sup>). The Court's constructions do not limit the average particle diameter measurement and the  $\pm 10\%$  deviation

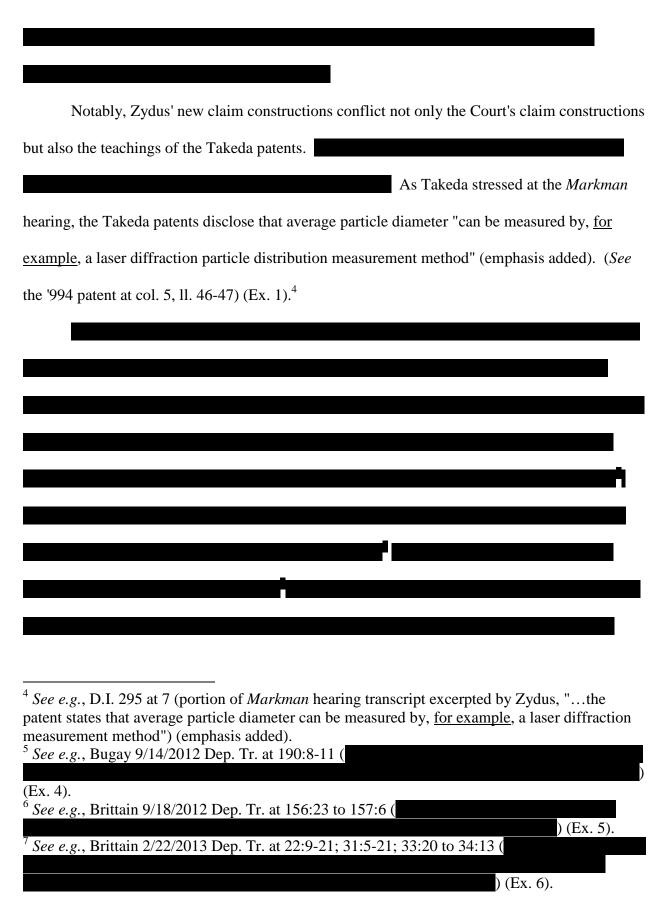
Nevertheless, Zydus advances new claim constructions with these limitations. (See D.I. 295 at 6-18). Thus, Zydus' new, litigation-driven claim constructions are specifically

tailored to carve out Plaintiffs' infringement

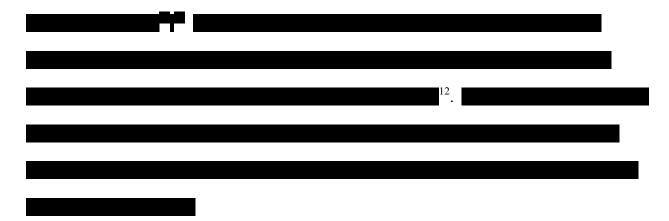
<sup>&</sup>lt;sup>1</sup> The Takeda patents consist of U.S. Pat. Nos. 6,328,994 ("the '994 patent") (Ex. 1); 7,431,942 ("the '942 patent") (Ex. 2); and 7,875,292 ("the '292 patent") (Ex. 3) (collectively "the Takeda patents"). References to exhibits herein refer to exhibits attached to the Declaration of Arlene L. Chow.

<sup>&</sup>lt;sup>2</sup> By stipulation of the parties and the Court's approval, the Court's *Markman* Order regarding the '994 and '942 patents were binding on the '292 patent; thus, the  $\pm 10\%$  deviation also applies to the relevant terms in the '292 patent. (*See* D.I. 97).

 $<sup>^3</sup>$  For example, the Court construed "fine granules having an average particle diameter of 400  $\mu$ m or less," which appears in claim 1 of the '994 patent, to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400  $\mu$ m ( $\pm 10\%$ ) or less." (*See* D.I. 113 at 7).



Second, Zydus asks the Court to weigh the evidence and exclude Plaintiffs' infringement testing Zydus' ANDA product based on conflicting testimony of the parties' experts. (See D.I. 295 at 18-23). But the purpose of a motion in limine is to determine whether evidence should be excluded altogether because of some evidentiary failing, not to argue the weight of the evidence. See Pfizer Inc. v. Teva Pharms. USA, Inc., 461 F. Supp. 2d 271, 275 (D.N.J. 2006). Weighing the evidence is more "appropriately addressed in cross examination [at trial] rather than in a motion in limine to preclude the evidence altogether." *Id.* For that reason alone, Zydus' argument should be rejected. <sup>8</sup> See e.g., testimony by Zydus' expert, Brittain 9/18/2012 Dep. Tr. at 58:15 to 59:25; 75:8-20; 76:2 to 77:5 (t (Ex. 5); see e.g., testimony by Takeda's expert, Bugay 9/14/2012 Dep. Tr. at 174:10 to 175:11 ( (Ex. 4) See U.S. Pharmacopeia ("USP") <429> at 1 see also testimony of Zydus' expert, Brittain 9/18/2012 Dep. Tr. at 18:20-25 ( (Ex. 5); see also Takeda's expert Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶33 (Ex. 8).



Zydus' Motion should be denied *in toto*. Zydus advances new claim constructions nearly one and a half years after this Court's *Markman* Order (*see* D.I. 113) and, contrary to the purpose of a motion *in limine*, Zydus asks the Court to weigh Plaintiffs' APD Evidence based on contradictory testimony of the parties' experts.

#### **ARGUMENT**

## I. Plaintiffs Properly

Zydus' attempt to reopen claim construction is untimely and improper. The Court already considered the parties' claim construction arguments during the claim construction briefing period, the *Markman* hearing, and in Zydus' motion for reconsideration. Nevertheless, Zydus advances new claim constructions further limiting the average particle diameter measurement and 10% deviation (See D.I.

295 at 11). Not only are Zydus' new claim constructions inconsistent with the Court's claim

constructions and the teachings of the Takeda patents,

) (Ex. 6).

<sup>&</sup>lt;sup>10</sup> See e.g., Meyer-Stout 9/12/2012 Dep. Tr. at 79:10-15 (

<sup>) (</sup>Ex. 9). <sup>1</sup> See USP <429> at 1

<sup>&</sup>lt;sup>2</sup> See e.g., testimony of Zydus' expert Brittain 2/22/2013 Dep. Tr. at 178:24 to 179:2

A. Zydus' new claim construction further limiting the average particle diameter measurement and 10% deviation is inconsistent with the Court's claim construction and the teachings of the Takeda patents

As the Court is aware, the asserted claims of the Takeda patents include a size limitation of the "fine granules." For each of these terms, the Court incorporated a  $\pm 10\%$  deviation to the average particle diameter measurement. (See D.I. 113 at 7, 9,  $10^{13}$ ). Clearly, none of the Court's constructions limit the measurement of the "fine granules" or the  $\pm 10\%$  deviation In addition, none of the Court's constructions limit the  $\pm 10\%$  deviation of the "fine granules"

It is worth noting that if Zydus wanted average particle size measurements and the 10% deviation it could have advanced a claim construction reflecting that. Zydus did not because it could not. The Takeda patents unambiguously teach

By stipulation of the parties and the Court's approval, the Court's *Markman* Order regarding the '994 and '942 patents were binding on the '292 patent; thus, the  $\pm 10\%$  deviation also applies to the relevant terms in the '292 patent. (*See* D.I. 97).

<sup>&</sup>lt;sup>14</sup> For example, the Court construed "fine granules having an average particle diameter of 400 μm or less," which appears in claim 1 of the '994 patent, to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 μm ( $\pm 10\%$ ) or less." (*See* D.I. 113 at 7).

<sup>&</sup>lt;sup>15</sup> Zydus even acknowledges that the Court already considered this argument – which Zydus pled during the *Markman* hearing – in rendering its claim construction opinion. (*See* D.I. 295 at 11-12). Nevertheless, Zydus seeks to revisit claim construction and re-argue this point.

<sup>&</sup>lt;sup>16</sup> See e.g., D.I. 295 at 7 (portion of *Markman* hearing transcript excerpted by Zydus, "...the patent states that average particle diameter can be measured by, <u>for example</u>, a laser diffraction measurement method") (emphasis added); D.I. 70 at 6 (quoting directly from the '994 patent specification at col. 5, Il. 46-47: "The '994 patent teaches that 'average particle diameter...can be measured by, for example, a laser diffraction particle distribution measurement method"

(See the '994 patent at col. 5, ll. 46-47
(average particle diameter "can be measured by, for example, a laser diffraction particle
distribution measurement method") (emphasis added) (Ex. 1)).
(See Meyer-Stout
9/12/2012 Dep. Tr. at 188:24 to 189:13) (Ex. 9).
During
the $Markman$ hearing, Plaintiffs noted the pharmaceutical industry's adoption of $\pm 10\%$ deviation
in particle size measurements, as reflected in the USP laser diffraction standard 17. In that way,
Takeda stressed that the 10% reflects a widely-accepted deviation for average particle size
measurements.
18
In short, the Takeda patents and the Court's claim construction permit
Zydus' ANDA product to make average particle diameter
measurements including the $\pm 10\%$ deviation pursuant to the Court's construction.

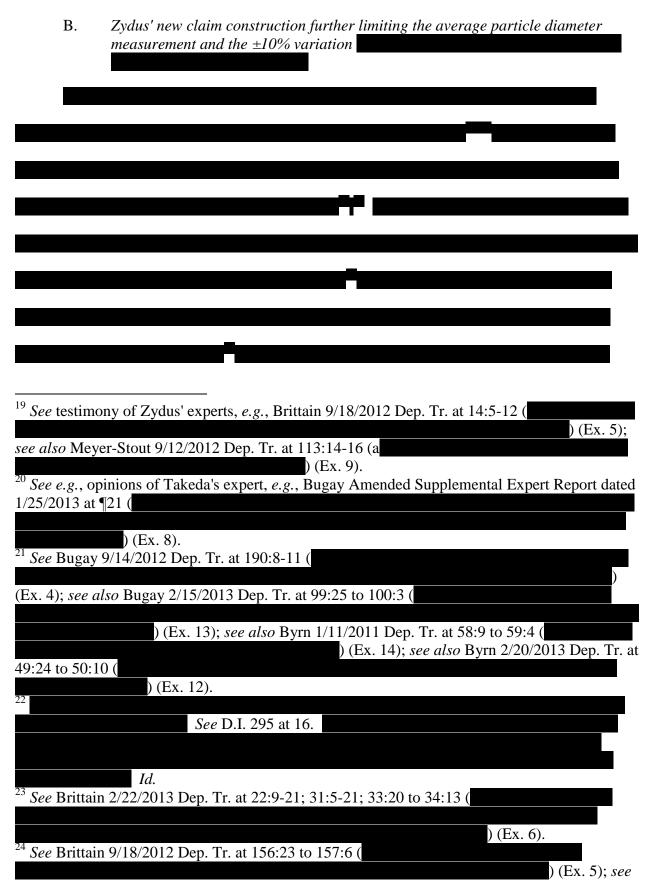
(emphasis added); *see also* Plaintiffs' *Markman* Hearing Presentation at Slide 11 (highlighting relevant portion of the '994 specification in yellow, including the specification's teaching that "[a]verage particle diameter...can be measured by, <u>for example</u>, a laser diffraction particle distribution measurement method") (emphasis added) (Ex. 10).

<sup>&</sup>lt;sup>17</sup> See 5/26/2011 Markman Hearing Tr. at 19:2-14 (showing PQRI's adoption of the USP standard of error of 10%) (Ex. 11); see also Plaintiffs' Markman Hearing Presentation at Slide 13 (Ex. 10).

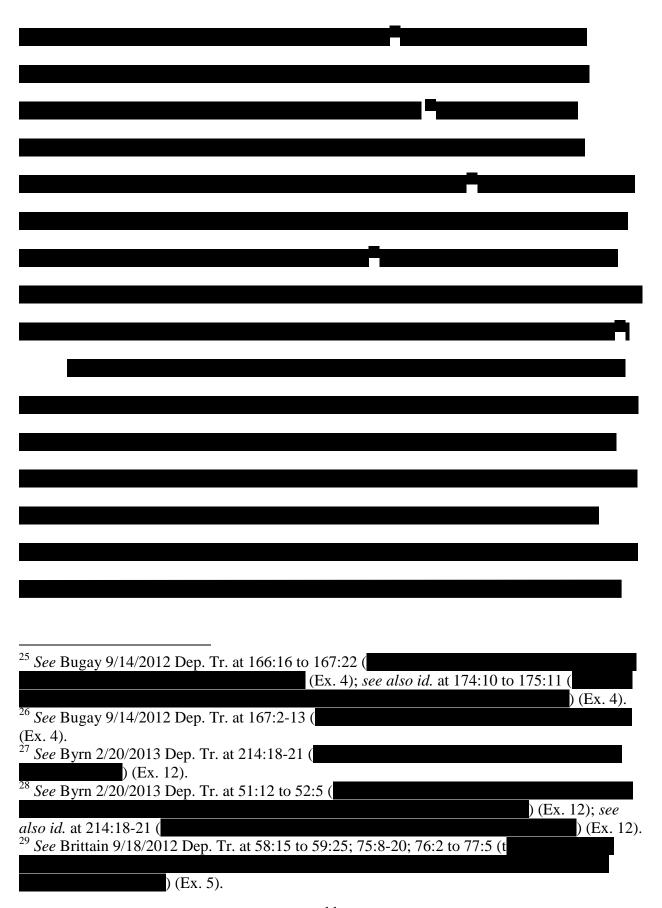
<sup>&</sup>lt;sup>18</sup> See Bugay 9/14/2012 Dep. Tr. at 190:8-11 (

(Ex. 4); see also Byrn 2/20/2013 Dep. Tr. at 49:24 to 50:10 (

(Ex. 12).



	(See Brittain 2/22/2013 Dep. Tr. at 34:16-
24; 38:8-13	(Ex. 6)).
In su	m, there is no basis for Zydus' new claim construction given
	for
measuring pa	article size.
C.	Zydus' new claim construction further limiting the $\pm 10\%$ variation
also Brittain	2/22/2013 Dep. Tr. at 23:3-13 (
	) (Ev. 6)



Zydus misrepresents the testimony of Plaintiffs' expert and counsel and stresses purported inconsistencies where there are none. (*See* D.I. 295 at 17-18). At the *Markman* hearing, Plaintiffs articulated that according to the USP, "laser diffraction incorporates a plus or minus ten percent standard of error and that takes into account, your Honor, the accuracy of instruments

percent standard of error and that takes into account, your Honor, the accuracy of instruments that measure laser diffraction" (emphasis added). (*See* 5/26/2011 *Markman* Hearing Tr. at p. 50:12-16 (Ex. 11)). Plaintiffs never represented that the 10% deviation is limited solely to instrumental error; given the uniformity of both side's experts that instrumental error is just one component of the 10% deviation, it would make no sense for Plaintiffs to do so. In fact, in opposing a 10% deviation, Zydus advanced a 3% instrumental error which the Court rejected, including on reconsideration. (*See*, e.g.,D.I. 116 at 14; D.I. 130)<sup>31</sup>. Because instrument error is just one component of the 10% variation, the 10% variation reflects – but is not limited to -- the "level of accuracy of those instruments." (*See* 5/26/2011 *Markman* Hearing Tr. at p. 50:19-23

(Ex. 11).

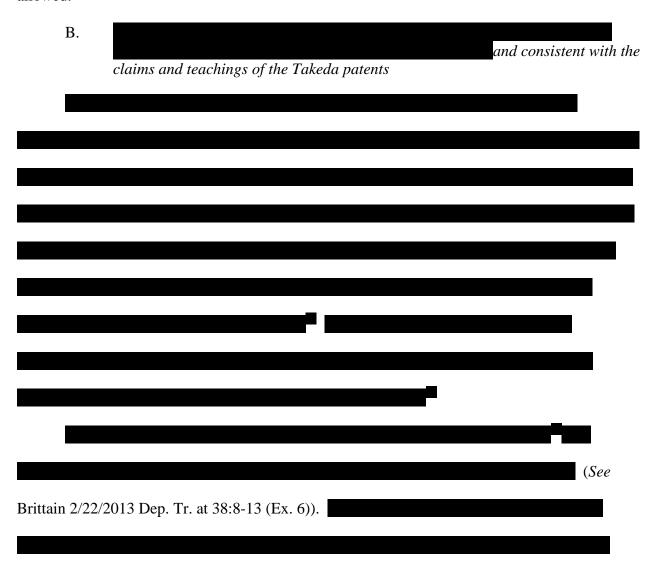
<sup>30</sup> 

<sup>(</sup>See D.I. 295 at 13-14); see also Bugay 9/14/2012 Dep. Tr. at 204:24 to 205:5; 205:15-21 (Ex. 4). Simply, variability in an unknown sample and inaccuracy of a known standard are two separate entities.

<sup>&</sup>lt;sup>31</sup> Zydus argued that the variation in the average particle diameter measurement should be limited to 3%, not 10%. (*See* D.I. 116 at 14). The section of the USP that Zydus relied on for the 3% figure addressed "confirm[ing] the correct operation of the instrument," which is instrumental error. (*See* D.I. 117 at 9).

	Given that Zydus'
Motiv	
	on is based on new claim constructions, this Court should reject that Motion on this basis
alone	
II.	Plaintiffs Properly
	A. is an issue for trial
	Zydus also asks the Court to weigh conflicting evidence between the parties' experts
	(See D.I. 295 at 20). That is improper for a
motic	on <i>in limine</i> . The purpose of a motion <i>in limine</i> is to decide the admissibility of evidence,

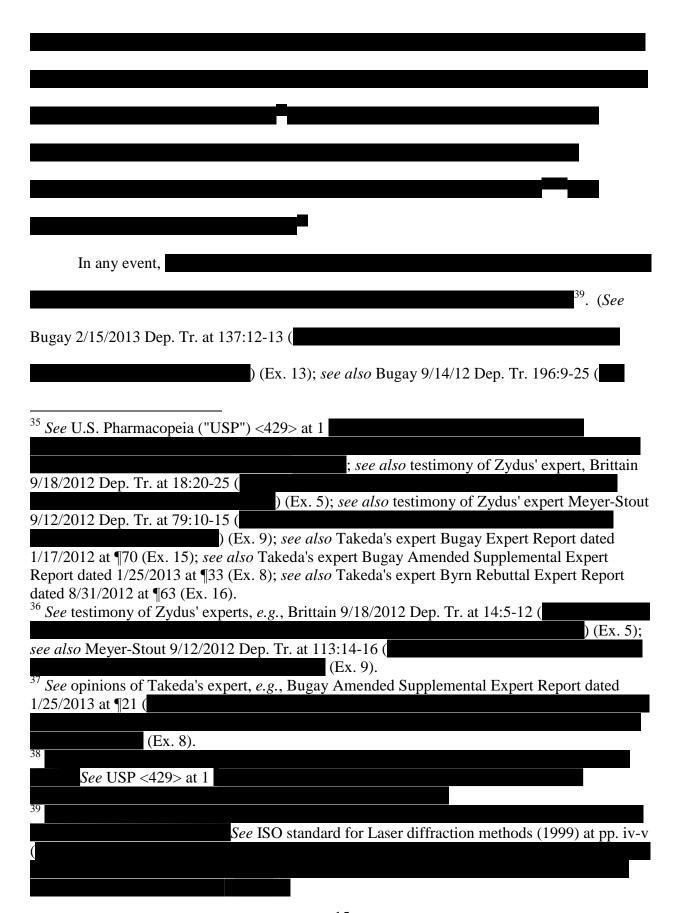
not to argue the weight of the evidence. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006). Weighing the evidence is more "appropriately addressed in cross examination [at trial] rather than in a motion in limine to preclude the evidence altogether." *Id.* For this reason alone, this argument should be rejected and Plaintiffs' APD Evidence should be allowed.

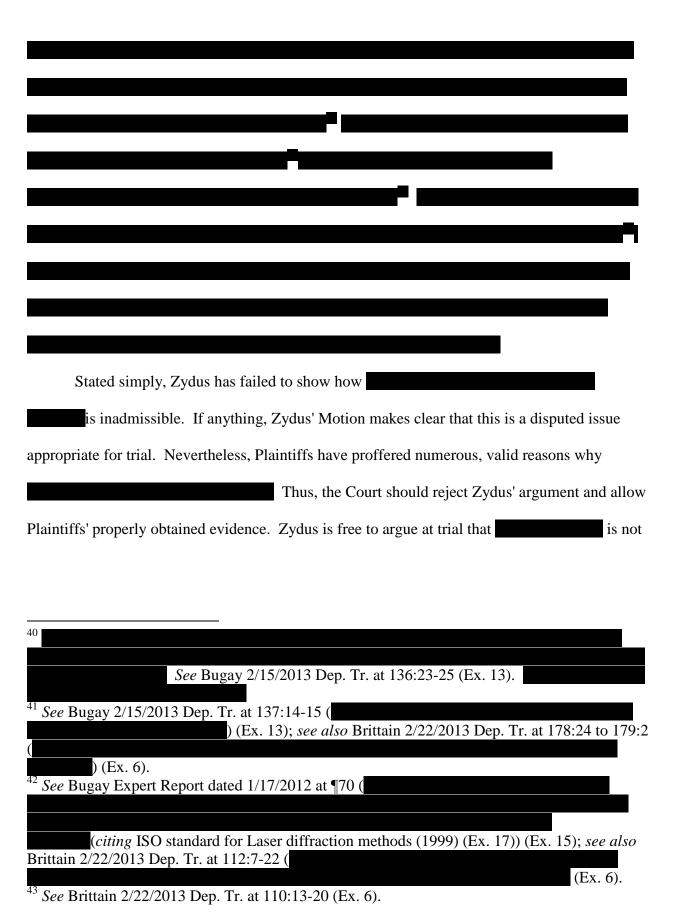


<sup>&</sup>lt;sup>32</sup> See the '994 patent at col. 15, 1.26 to col. 16, 1. 27 (Ex. 1); see also the '942 patent, at col. 15, 1. 10 to col. 16, 1. 3 (Ex. 2); see also the '292 patent, at col. 15, 1. 16 – col. 16, 1. 10 (Ex. 3).

<sup>&</sup>lt;sup>33</sup> See Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶18-19 (Ex. 8); see also Byrn 2/20/2013 Dep. Tr. at 96:11-14; 96:23 to 97:2 (Ex. 12).

<sup>&</sup>lt;sup>34</sup> See Bugay Expert Report dated 1/17/2012 at ¶55 (Ex. 15).





warranted, and Plaintiffs will argue the opposite. But that is a matter of proof, not a motion *in limine*.

### **CONCLUSION**

For the reasons stated above, Zydus has failed to show that excluding Plaintiffs' APD Evidence is warranted. Accordingly, Plaintiffs respectfully submit that the Court deny Zydus' MIL *in toto*.

Respectfully submitted,

By: <u>s/John E. Flaherty</u> John E. Flaherty Jonathan M.H. Short

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Dated: March 7, 2013

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